



Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10465 and CMS-10495]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number: _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing)

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10465 Minimum Essential Coverage

CMS-10495 Data Collection and Submission, Registration, Attestation, Dispute and Resolution, Record Retention, and Assumptions Document Submission, for Open Payments

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit

reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Minimum Essential Coverage; *Use:* The final rule titled “Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions,” published July 1, 2013 (78 FR 39494) designates certain types of health coverage as minimum essential coverage. Other types of coverage, not statutorily designated and not designated as minimum essential coverage in regulation, may be recognized by the Secretary of Health and Human Services (HHS) as minimum essential coverage if certain substantive and procedural requirements are met. To be recognized as minimum essential coverage, the coverage must offer substantially the same consumer protections as those enumerated in the Title I of the Affordable Care Act relating to non-grandfathered, individual health insurance coverage to ensure consumers are receiving adequate coverage. The final rule requires sponsors of other coverage that seek to have such coverage recognized as minimum essential coverage to adhere to certain procedures. Sponsoring organizations must submit to HHS certain information about their coverage and an attestation that the plan substantially complies with the provisions of Title I of the Affordable Care Act applicable to non-grandfathered individual health insurance coverage. Sponsors must also provide notice to enrollees informing them that the plan has been recognized as minimum essential coverage. *Form Number:* CMS-10465 (OMB Control Number 0938-1189); *Frequency:* Occasionally; *Affected Public:* Public and Private sectors; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 52.5. (For policy questions regarding this collection

contact Russell Tipps at 301-492-4371.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Registration, Attestation, Dispute Resolution and Correction, Assumptions Document and Data Retention Requirements for Open Payments; *Use:* The Patient Protection and Affordable Care Act was enacted on March 23, 2010 (Pub. L. 111-148). This statute amended section 1128 of the Social Security Act (the Act) by adding a new subsection G that requires applicable manufacturers of drugs, devices, biologics, or medical supplies covered under title XVIII of the Act (Medicare) or a State plan under title XIX (Medicaid) or XXI of the Act (the Children's Health Insurance Program, or CHIP) to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals. Section 1128G of the Act also requires applicable manufacturers and applicable group purchasing organizations (GPOs) to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities, as well as any payments provided to such physicians. The submitted information facilitates various aspects of the program. The information collected through the registration process is used by CMS to validate registration for applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors that are registering for Open Payments. Details collected during the dispute resolution and correction process allows CMS to notify applicable manufacturers and applicable GPOs that a covered recipient or physician owner or investor is initiating a dispute regarding data submitted about them and allow CMS to relay the nature of the dispute. The assumptions documents submitted by applicable manufacturers or applicable GPOs assist CMS in providing guidance (for example, determining form and nature of payment categories, calculating the value of a payment, determining the date of payment, and reporting the terms of an ownership or investment interest). *Form Number:* CMS-10495 (OMB control number: 0938-1237); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 1,612; *Total Annual Responses:* 1,612; *Total Annual*

Hours: 1,920,534. (For policy questions regarding this collection contact Kathleen Ott at 410-786-4246.)

Dated: April 7, 2022.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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